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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,199	12/21/2001	Claudio De Simone	2818-72	4379

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/024,199

Applicant(s)
Simone

Examiner
Deborah Ware

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 21, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other: _____

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Claims 1-18 are presented for examination on the merits.

The Information Disclosure Statement filed December 21, 2001 has been received and entered. The references submitted therewith have been considered as indicated on the enclosed PTO-1449 Form.

Further, the Preliminary amendments filed December 21, 2001, have been received and entered.

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on June 21, 1999. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b). Therefore, foreign priority has not been perfected. Also it is noted that the instant application is a continuation of international application PCT/IT00/00251 filed June 16, 2000 and such amendment at page 1, line 1 of the specification is noted. The benefit of priority to the PCT Application is noted. However, there is not indication in the file that a copy of the certified foreign document has been filed in the PCT either, thus, the foreign priority is acknowledged and noted that entire copy is incorporated by reference. However, a certified copy of the foreign priority document should be received in either the instant file since it does not appear that a copy was filed in the international stage of the PCT. Applicants are requested to file the certified copy of the foreign priority document or clarify on the record if one has been filed or not.
2. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

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Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.

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- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

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However, in the instant case It is noted that applicants have deposited the organism, note page 3 and claim 2, but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of

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the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- | | |
|--|--|
| (1) The name and address of the depository;
the depository; | (2) The name and address of
the depository; |
| (3) The date of deposit;
of the deposit and the accession number given by the depository; | (4) The identity
of the deposit and the accession number given by the depository; |
| (5) The date of the viability test;
sample if the test is not done by the depository; and
that the deposit is capable of reproduction. | (6) The procedures used to obtain a
sample if the test is not done by the depository; and
that the deposit is capable of reproduction. |
| | (7) A statement
that the deposit is capable of reproduction. |

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite for the long recitation of information regarding the strain "CD2" of which is unnecessary in the claim. Applicant need only identify the strain as --DSM 11988-- wherein it is suggested to delete "CD2 strain deposited in the DSM - number" and also delete "under the Budapest Treaty, or mutants or derivatives thereof". Also it is suggested to delete "the" and insert --biologically pure-- in front of the "*Lactobacillus brevis*".

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Further, recitation of "or mutants or derivatives thereof" is unclear as to what is intended in the claim by such terminology. Thus, it is suggested to delete this phraseology entirely.

Claim 3 is rendered vague and indefinite for the recitation of "according to Claims 1" and "is from 1:00 to 100:1" is unclear since there not more than one Claim 1, thus, the first recitation rejected must be a typo and the ratio is unclear since "1:00" is not clear and most likely is a typo too and should be --1:100-- so the ratio would therefore, read as --1:100 to 100:1--. Proper support could not be found for the ratio in the specification. However, it is not deemed new matter at this time since it appears to be a typo. Corrections are requested.

Claims 4-5 are rendered vague and indefinite for reasons set forth above for claim 3.

Claim 6 is rendered vague and indefinite for "unit dosage units" wherein is unclear since the term is redundant and would read better as "dosage units". However, in order to be consistent with claim 7 perhaps "unit dosage units" should be deleted entirely.

Claim 8 is rendered vague and indefinite for "sucking tablets" and "tablets" since it is unclear how the "sucking tablets" differ from "tablets". Clarification is requested with appropriate support in the specification that other tablets than "sucking tablets" are disclosed, for example. Otherwise deletion of "tablets" is requested.

Claims 15-16 and 18 are rendered vague and indefinite for the recitation of "The composition" which appears to lack antecedent basis in the claims. The term should be changed to --Combination--

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5. Claims 12 and 13-14 provide for the use of combination of lactic acid bacteria, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Also the recitation of the term "especially" in the claims renders the claims indefinite.

6. Claim 10 is rendered vague and indefinite for the recitation of "to any one of the previous claims" since it is uncertain which *claim is referred to*.

Claims 12 and 13-14 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-18 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 956 858 A1, cited on the enclosed PTO-1449 Form.

Claims are drawn to combination compositions of Lactobacilli bacteria.

The EP Patent is also drawn to combinations of compositions of Lactobacilli bacteria of which appears to read on each of the claims herein. Note the abstract and page 2, lines 45-55, and page 3, lines 50-55 and Table 1 and 2 of page 5, also pages 6-9, all lines.

The claims are identical to the disclosure of the above cited EP patent and therefore, are considered to be anticipated by the teachings of the cited reference. However, in the alternative that there is some unidentified claim characteristic then the characteristic is considered to be such a slight difference as to render the claims obvious over the cited reference. Note also that many Lactobacilli use arginine and such characteristic is inherent to the cited disclosure. Thus, even if the characteristic or perhaps another unidentified one is set forth by Applicant as providing for some difference between what is claimed and disclosed for which to remove the reference as a valid 102 reference, then the difference is considered to be so slight as to render the claims obvious over the reference. One of ordinary skill in the art would have been motivated from the teachings at the very least of the EP citation to provide for combinations of Lactobacilli as claimed herein. The claims are alternatively prima facie obvious.

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10. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP, cited above, in view of WO 99/42568, other citation on the enclosed PTO-1449 Form.

The claims and EP citation are discussed above.

WO 99/42568 clearly teach arginine activity by lactobacillus bacteria, see the abstract.

The claims may be alternatively different than EP citation in that the EP appears to be silent with respect to arginine activity of Lactobacilli. However, as discussed above the characteristic is believed by the examiner to be an inherent characteristic of the bacteria. Even so, if Applicant are able to show there is a difference then it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of the cited reference to provide for combinations of Lactobacilli having arginine activity. Such selection by one of skill in the art would have been motivated by the teachings of the WO patent cite, noted above. Clearly one of skill would have expected successful results with selection of Lactobacilli having arginine activity. The claims are also deemed prima facie obvious over this combined art reference rejection as well as the EP reference as cited above all by itself. The claims are rendered at least prima facie obvious for these reasons and those reasons noted above.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

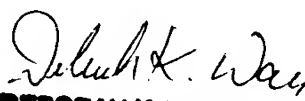
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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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July 12, 2002